

CLAIMS

WHAT IS CLAIMED IS:

1. A consumable film adapted to adhere to and dissolve in a mouth of a consumer, wherein said film comprises at least one water soluble polymer and an antimicrobial effective amount of at least one essential oil selected from the group consisting of thymol, methyl salicylate, eucalyptol and menthol.
2. The consumable film according to claim 1, comprising at least two of said essential oils.
3. The consumable film according to claim 1, comprising at least three of said essential oils.
4. The consumable film according to claim 1, comprising thymol, methyl salicylate, eucalyptol and menthol.
5. The consumable film according to claim 4, further comprising a salt of gluconic acid.
6. The consumable film according to claim 4, further comprising copper gluconate.
7. The consumable film according to claim 1, wherein said water soluble polymer is selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid,

methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, dextrin, pectin, chitin, chitosan, levan, elsinan, collagen, gelatin, zein, gluten, soy protein isolate, whey protein isolate, casein and mixtures thereof.

5 8. The consumable film according to claim 7, wherein said water soluble polymer is pullulan.

9. The consumable film of claim 8, comprising:

about 40 to about 80 wt % pullulan;

about 0.01 to about 4 wt % thymol;

about 0.01 to about 4 wt % methyl salicylate;

about 0.01 to about 4 wt % eucalyptol; and

about 0.01 to about 15 wt % menthol.

10. The consumable film according to claim 7, further comprising:

about 0.01 to about 5 wt % of at least one stabilizing agent;

about 0.001 to about 0.1 wt % of at least one of at least one coloring agent;

about 0.1 to about 8 wt % of water;

about 0.1 to about 15 wt % of at least one sweetening agent;

about 0.1 to about 15 wt % of at least one flavoring agent;

20 about 0.1 to about 4 wt % of at least one cooling agent; and

about 0.1 to about 5 wt % of at least one surfactant.

11. The consumable film according to claim 10, wherein said least one stabilizing agent is selected from the group consisting of xanthan gum, locust bean gum and carrageenan, and said at least one sweetening agent is selected from the group consisting of saccharin, aspartame and acesulfame K.

5 12. The consumable film according to claim 1, wherein said film does not substantially adhere to itself.

13. The consumable film according to claim 1, wherein said film is free of glycerin and sorbitol.

14. The consumable film according to claim 1, wherein said film is free of humectants.

15. The consumable film according to claim 1, wherein the essential oils comprises at least about 10 wt % of the film.

16. The consumable film according to claim 15, wherein the essential oils comprises at least about 15 wt % of the film.

17. The consumable film according to claim 1, further comprising water in an amount from about 3 wt % to about 8 wt %.

18. A method for preparing a physiologically compatible film, said method comprising:

20 mixing at least one water soluble film former and at least one stabilizing agent to provide a film-forming mixture;

dissolving water-soluble ingredients in water to provide an aqueous solution;

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xanthan gum
locust bean gum
carrageenan

combining said film-forming mixture and said aqueous solution to provide a
hydrated polymer gel;

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5 mixing oils to form an oil mixture;

adding said oil mixture to said hydrated polymer gel and mixing to provide a
uniform gel;

casting the uniform gel on a substrate; and

drying the cast gel to provide said film.

19. The method according to claim 18, wherein at least one surfactant is
mixed into said oil mixture.

10 20. The method according to claim 18, wherein the total amount of said oils
in said oil mixture is at least about 5 wt % of the total weight of ingredients in said
method.

21. The method according to claim 20, wherein said total amount of oils is
at least about 15 wt %.

15 22. The method according to claim 18, wherein said drying is conducted
until said film has a moisture content of about 3 wt % to about 8 wt %.

23. The method according to claim 18, wherein, prior to being combined
with said aqueous solution, said film-forming mixture is hydrated with water at a
temperature of about 25 to about 50°C and subsequently chilled to a temperature of
20 about 4 to about 30°C for about 2 to 48 hours.

24. The method according to claim 18, wherein said film-forming mixture is

a powder, which is directly combined with said aqueous solution.

25. The method according to claim 24, wherein said hydrated polymer gel is formed without heating. *See 27 not critical?*

26. The method according to claim 25, wherein said hydrated polymer gel is 5 stirred at room temperature for about 2 to about 48 hours.

27. The method according to claim 26, wherein said oil mixture is prepared by mixing thymol and menthol in a flavor oil, and subsequently adding methyl salicylate and eucalyptol.

~~28. A non-self-adhering film produced according to the method of claim 18.~~

29. The method according to claim 18, wherein the water soluble film former is selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, tragacanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, dextrin, pectin, chitin, chitosan, levan, elsinan, collagen, gelatin, zein, gluten, soy protein isolate, whey protein isolate, casein and mixtures thereof.

30. The method according to claim 29, wherein said water soluble polymer 20 is pullulan.

31. A consumable film adapted to dissolve in the mouth of a consumer,

wherein said film comprises a single layer including pullulan and at least one pharmaceutical agent.

32. The consumable film according to claim 31, wherein said pharmaceutical agent is selected from the group consisting of antimicrobial agents, 5 non-steroidal anti-inflammatory agents, anti-tussives, decongestants, anti-histamines, expectorants, anti-diaherrals, H₂-antagonists, proton pump inhibitors, central nervous system agents, analgesics, and mixtures thereof.

33. The consumable film according to claim 32, wherein the antimicrobial agent is selected from the group consisting of triclosan, cetyl pyridium chloride, domiphen bromide, quaternary ammonium salts, zinc compounds, sanguinarine, fluorides, alexidine, octonidine, EDTA and mixtures thereof.

34. The consumable film according to claim 32, wherein the non-steroidal anti-inflammatory agent is selected from the group consisting of aspirin, acetaminophen, ibuprofen, diflunisal, fenoprofen calcium, naproxen, tolmetin sodium, 15 indomethacin, and mixtures thereof.

35. The consumable film according to claim 32, wherein the anti-tussive is selected from the group consisting of benzonatate, caramiphen edisylate, dextromethorphan hydrobromide, chlorpheniramine maleate and mixtures thereof.

36. The consumable film according to claim 32, wherein the decongestant is selected from the group consisting of pseudoephedrine hydrochloride, phenylephrine, 20 phenylpropanolamine and mixtures thereof.

37. The consumable film according to claim 32, wherein the anti-histamine is selected from the group consisting of brompheniramine maleate, chlorpheniramine maleate, carboxamine maleate, clemastine fumarate, dexchlorpheniramine maleate, diphenhydramine hydrochloride, diphenhydramine citrate, diphenylpyraline hydrochloride, doxylamine succinate, promethazine hydrochloride, pyrilamine maleate, triphenenamine citrate, triprolidine hydrochloride and mixtures thereof.

5 38. The consumable film according to claim 32, wherein the expectorant is selected from the group consisting of guaifenesin, ipecac, potassium iodide, terpin hydrate and mixtures thereof.

40 39. The consumable film according to claim 32, wherein the anti-diarrheal is loperamide.

45 40. The consumable film according to claim 32, wherein the H₂-antagonist is selected from the group consisting of famotidine, ranitidine and mixtures thereof.

41. The consumable film according to claim 32, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, and mixtures thereof.

20 42. A method for delivering and enhancing the retention of an effective amount of an antimicrobial agent to the oral cavity comprising introducing in the oral cavity a rapidly dissolving film comprising pullulan and an antimicrobial agent comprising menthol and at least one of methyl salicylate, eucalyptol and thymol, wherein said pullulan enhances the retention of the antimicrobial agent in the oral

cavity.

43. The method according to claim 42, wherein the antimicrobial agent comprises menthol, methyl salicylate, eucalyptol and thymol.

44. The method according to claim 42, wherein the amount of pullulan in
5 the film is from about 40 wt% to about 80 wt %.

45. The method according to claim 42, wherein the amount of antimicrobial agent in the film is from about 5 wt% to about 12 wt%.

46. The method according to claim 43, wherein the amount of antimicrobial agent in the film is from about 5 wt % to about 12 wt%.

47. A method for delivering and enhancing the retention of an effective amount of an antimicrobial agent to the oral cavity comprising introducing in the oral cavity the consumable film according to claim 9.

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